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| APPLICATION NO.                                     | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.             | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------------------|------------------|
| 10/797,565  | 03/11/2004  | Steven M. Griffiths  | 11201-735-999                   | 4820             |
| 20583   | 7550        | 02/19/2008           |                                 |                  |
| JONES DAY<br>222 EAST 41ST ST<br>NEW YORK, NY 10017 |             |                      | EXAMINER<br>MACNEILL, ELIZABETH |                  |
|   |             |                      | ART UNIT                        | PAPER NUMBER     |
|   |             |                      | 3767                            |                  |
|   |             |                      | MAIL DATE                       | DELIVERY MODE    |
|   |             |                      | 02/19/2008 PAPER                |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/797,565

**Applicant(s)**

GRIFFITHS, STEVEN M.

**Examiner**

ELIZABETH R. MACNEILL

**Art Unit**

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**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 01 February 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 9-16 and 18-27 is/are pending in the application.
- 4a) Of the above claim(s) 22-27 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7, 9-16 and 18-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/S508)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_
- Paper No(s)/Mail Date \_\_\_\_\_

## DETAILED ACTION

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1 February 2008 has been entered.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 2, 7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kruck (US 3,974,832)

4. Regarding claim 1, Kruck teaches (**see embodiment of Fig 1**) a needle and hub assembly for an injection device, comprising: a cap (26) having an engaging portion (28) adapted to engage an exterior surface of a cartridge (12), and a needle-supporting portion having a wall with a front surface (38,40) that includes an opening therein, the wall defining interior and exterior surfaces (Fig 1); a first hub portion (48) defining a needle-receiving channel (51,53) through the opening in the wall and having a section that extends along the interior surface of the wall (54,56); a needle (24) mounted in the

needle-receiving channel and extending outwardly therefrom; and a second hub portion (46) engaged with the first hub portion (around 30) and receiving at least a portion of the needle (supporting portion at 55), the second hub portion having reinforcing structures (50, 52) which extend outwardly along the exterior surface of the wall; wherein the wall of the needle-supporting portion of the cap is reinforced on the interior surface by the first hub portion and on the exterior surface by the second hub portion. See Figure 1. As to claim 2, the first and second hubs are fused by press fit. Regarding claim 9, the needle-receiving channel provides a continuous flow pathway from the inside of the cap to the outside of the cap (via needle lumen).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 3-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruck.

Kruck teaches the assembly as above. Regarding claims 3-6, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use metal and plastic to form the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

7. Claims 10-16 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruck in view of Sarnoff et al (US 4,755,169).

Regarding claim 10, Kruck teaches a needle and hub assembly for an injection device, as described above. Kruck fails to teach that the assembly is used with an automatic injector with a stored energy source.

Sarnoff teaches an automatic injector with a hub assembly (526), plunger (558), cartridge (546) and a stored energy means (spring 564). See Figs 10-13

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the stored energy means of Sarnoff with the hub assembly of Kruck in order to provide a means for automatically injecting a medicament into a patient by applying less force to the plunger (i.e. allowing the stored energy means to provide force to the plunger).

Regarding claims 12-15, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use metal and plastic to form the device, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice.

*In re Leshin*, 125 USPQ 416.

Regarding claim 19, the cartridge has two medicament compartments (552, 540, Sarnoff).

Regarding claim 20, one of the medicament compartments is adapted to house a wet medicament component (552) and the other medicament compartment is adapted to house a dry medicament compartment (540, Sarnoff).

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Regarding claim 21, the at least one opening in the cartridge is in the dry medicament compartment (Sarnoff Fig 10).

***Response to Arguments***

Applicant's arguments are moot in view of the new grounds of rejection.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

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/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767